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Case Docket No. 1171/38911/80

BOX: PATENT APPLICATION  
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Sir:

Transmitted herewith for filing is the patent application of

Inventor: NICHOLAS CHARLES ALAN SMITH  
 ALASTAIR EDWIN McAULEY

For: **Breathing Assistance Apparatus**

Enclosed are:

- ☒ Four (4) informal sheets of drawings.
- ☒ An unexecuted Declaration and Power of Attorney for Patent Application.

The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)
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INDEP. CLAIMS	2 - 3 =	* 0
<input checked="" type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENTED		

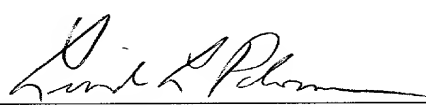
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x 39 =	\$
+130 =	\$
TOTAL	\$

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Dated: September 14, 2000

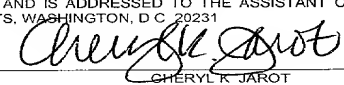
  
 Linda L. Palomar, Reg. No. 37,903  
 Attorney of Record

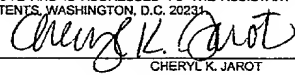
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- 1 -

## BREATHING ASSISTANCE APPARATUS

### BACKGROUND TO THE INVENTION

#### i) Field of the Invention

5           This invention relates to valves particularly through not solely for inclusion in the breathing circuit of a respirator.

#### ii) Summary of the Prior Art

10           A medical breathing circuit such as might be used in a Continuous Positive Airway Pressure Respirator (CPAP) includes an inspiratory gases tube which has one end thereof connected to the patient through an interface. For example through an endotracheal breathing tube extending into the trachea and ending just above the lungs. The other end thereof is connected to a respirator providing pressurised gases. The connection to the respirator may be direct or a self contained humidifier may be interposed.

15           One disadvantage of CPAP treatment is that it effectively reverses the normal breathing function. The patient has to relax to breath in and requires effort to breath out. Since normal breathing requires the exact opposite, the use of CPAP is sometimes difficult initially.

20           A number of devices exist to reduce the effort required by the patient to exhale. For example US Patent 5,657,752 assigned to Airways Associates describes a variable orifice venting aperture member in the nasal mask to help vent the exhalations. US Patent Number 5,065,756 assigned to New York University includes vent holes in the face mask for rapid discharge of exhaled air. US Patent 4,658,213 assigned to New York University includes a threshold valve to release air from the mask. Alternatively electronic methods exist such as that described in US Patent 5803065 assigned to Respironics have been used to improve the effectiveness of CPAP therapy.

25           However to some degree these existing devices are still somewhat ineffective. Also in some cases these apparatus include a bulky face mask and strapping which may be uncomfortable for the user.

### SUMMARY OF THE INVENTION

30           It is an object of the present invention to provide a valve for a respiratory breathing circuit which will obviate the above disadvantage or will at least provide healthcare providers with a useful choice.

          Accordingly in a first aspect the invention consists in a device for controlling the gas flow between a pressurised gases supply and a user, comprising:

a body portion including a first opening adapted to be in fluid communication with a pressurised gases supply, a second opening adapted to be in fluid communication with a user a first auxiliary outlet in said body portion, and

5 valve means adapted such that during a user's inhalation, the flow of gases from said first opening is directed to said second opening, and during a user's exhalation, the flow of gases from said first opening is directed to said first auxiliary outlet.

10 In a second aspect the present invention consists in a system for supplying gases to a user at a pressure above ambient including a pressurised gases supply; gases delivery means for supplying said gases to said user in fluid communication with said pressurised gases supply and said user; and flow control means disposed within said gases delivery means or in fluid communication therewith, said flow control means comprising:

a body portion including a first opening adapted to be in fluid communication with said pressurised gases supply, a second opening adapted to be in fluid communication with said user a first auxiliary outlet in said body portion, and

15 valve means adapted such that during said user's inhalation, the flow of gases from said first opening is directed to said second opening, and during said user's exhalation, the flow of gases from said first opening is directed to said first auxiliary outlet.

20 To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

25 Figure 1A is a blown out perspective view of the present invention, showing the components that fit together to form the valve,

Figure 1B is a blown out perspective view of the movable valve member according to the preferred embodiment of the present invention,

Figure 2 is a cutaway view of the present invention during inhalation,

30 Figure 3 is a cutaway view of the present invention during exhalation,

Figure 4 is a graph of a typical pressure/flow rate characteristics of a respirator,

Figure 5 is a block diagram of a typical breathing assistance apparatus circuit, according to the preferred embodiment of the present invention,

Figure 6 is a graph illustrating the typical pressure profile experienced by a patient

according to traditional CPAP methods, and

Figure 7 is a graph illustrating the typical pressure profile experienced by a patient according to the preferred embodiment of the present invention.

## 5 DETAILED DESCRIPTION

The present invention attempts to provide a simple to manufacture device which attempts to improve comfort levels for a user undergoing CPAP therapy. This is done by providing a four-way valve in the conduit between the respirator and the patient which allows both gases to flow to the patient and exhalations to be expelled to flow through the same conduit. This makes exhaling easier for the user, without the need for additional apparatus to be worn by the user. If the gases supplied to the user are to be humidified, the valve is positioned between the respirator and the humidifier, i.e. upstream of the humidifier.

Referring now to Figure 1, we see the valve in more detail. The valve body 100 has two ends 102, 104 adapted for connection to a typical respiratory conduit and an enlarged centre section 106 which houses the axially moveable valve member 108. The centre section 106 includes two apertures 110 and 112 on its periphery, located either side of an imaginary central point.

The valve member 108 is of a generally hollow cylindrical construction and includes two matching apertures 114, 116 on its periphery again located either side of an imaginary centre point. Also part of the valve member 108 is a partition 118 which joined to the inner periphery of the valve member in between the two apertures 114, 116. Attached in the centre 122 of the partition 118 is a one-way valve 120 which only allows inhalatory gases to pass and at least partially blocks exhalatory gases.

In the preferred embodiment of the present invention the one way valve 120 is a sealing rubber flap attached to the partition on the patient side. This allows gas to pass from respirator to user (inhalation), but only on a minimal level from user to respirator (exhalation) in Figures 2 and 3. This is because the flap is designed to be not quite large enough to entirely seal around the aperture. Thus a small amount of exhalatory gases may pass.

Referring now to Figures 2 and 3, the operation of the valve is now explained.

During a patient inhalation the valve member is in the open position as shown in Figure 2. The gas flow is as designated by arrow 130, which forces the movable member 108 towards the patient, until it hits the inspiratory stops 134. The apertures in the body portion 110, 112 in this position are closed off and do not match up with the apertures in the valve member 114, 116. In this case the one-way valve is effectively in open position and provides low resistance

through the valve from the respirator to the patient.

When the patient exhales, shown in Figure 3, back pressure results on the patient side of the valve due to the one-way valve 120. This pressure forces the valve member 108 to move towards the respirator, until it hits the expiratory stops 136. Once forced to the "closed" position, the apertures 110, 112 in the body portion and the apertures in the valve member 114, 116 align. This means that gases from the respirator are discharged into the atmosphere, shown by arrow 140 and the exhalatory gases from the patient, shown by arrow 150, are also discharged into the atmosphere. This means that the back pressure that the patient experiences while exhaling is much reduced due to the typical pressure flow rate characteristics of the respirator shown in Figure 4. During inhalation the respirator might operate at point 200. Whereas during exhalation, due to the high flow rate through aperture 110 into the atmosphere, operation might be at point 202 with correspondingly low pressure seen by the patient.

It will be appreciated that the aperture in the valve used to vent the patient's exhalations is only one possible embodiment of the present invention. It would be equally viable to have, for example, a pressure release valve in the circuit near the patient. The advantage of the present invention however is the reduced pressure delivered by the respirator, during exhalation.

Each of the valve body portion 102 and valve member 108 may be simply manufactured by injection moulding, for example a polycarbonate plastics material or other suitable plastics material.

A typical respiratory humidification circuit such as might employ the present invention is shown diagrammatically in Figure 5, and includes the respirator 230, humidifier 231, and the associated respiratory breathing tubes 233 and 234. A patient 236 under treatment is shown connected to the system. As indicated in Figure 5 the valve of the present invention is connected between the humidifier 231 and the outlet port of the respirator 230 and is indicated by reference numeral 237.

A typical pressure profile as might be experienced by a patient treated using the present invention is shown in Figure 7. This illustrates the high pressure during inhalation 300, the point at which the valve vents the respirator output 301, and the relatively low pressure during exhalation 302. This compares with a typical pressure profile of a patient treated without the present invention shown in Figure 6. This illustrates that the pressure experienced during exhalation 308 is similar to that during inhalation 306.

It will be appreciated from the above description that during exhalation the patient does not have to exert as much force to exhale as would normally be the case with traditional CPAP

Table 1. Demographic characteristics of the study population	
Age (years)	65.0 ± 10.0
Gender	
Male	50 (50.0%)
Female	50 (50.0%)
Marital status	
Married	40 (80.0%)
Single	10 (20.0%)
Education level	
High school or above	30 (60.0%)
Below high school	20 (40.0%)
Occupation	
Retired	30 (60.0%)
Unemployed	20 (40.0%)
Income (USD/month)	
< 1000	10 (20.0%)
1000-2000	20 (40.0%)
> 2000	20 (40.0%)
Comorbidities	
Hypertension	30 (60.0%)
Diabetes	10 (20.0%)
Cholesterol	20 (40.0%)
Smoking status	
Smoker	10 (20.0%)
Non-smoker	40 (80.0%)
Alcohol consumption	
Drinker	10 (20.0%)
Non-drinker	40 (80.0%)
Medication use	
Antihypertensive	30 (60.0%)
Antidiabetic	10 (20.0%)
Lipid-lowering	20 (40.0%)
Cardiovascular	10 (20.0%)
Other	10 (20.0%)

**CLAIMS:**

1. A device for controlling the gas flow between a pressurised gases supply and a user, comprising:
- 5 a body portion including a first opening adapted to be in fluid communication with a pressurised gases supply, a second opening adapted to be in fluid communication with a user a first auxiliary outlet in said body portion, and valve means adapted such that during a user's inhalation, the flow of gases from said first opening is directed to said second opening, and during a user's exhalation, the flow of
- 10 gases from said first opening is directed to said first auxiliary outlet.
2. A device as claimed in claim 1 further comprising a second auxiliary outlet in said body portion, which during inhalation of a user is closed, and during exhalation of a user is open and in fluid communication with said second opening.
- 15 3. A device as claimed in claims 1 or 2 wherein said valve means comprises an axially moveable member of a construction suitable to substantially seal inside said body portion but in use axially moveable therein.
- 20 4. A device as claimed in claim 3 wherein said movable member including at least two apertures and said first auxiliary outlet and said second auxiliary outlet comprise apertures in said body portion which align with said apertures in said moveable member during exhalation of a user, and are closed off by solid sections of said moveable member during inhalation of a user.
- 25 5. A device as claimed in claims 3 or 4 wherein said moveable member includes a partition disposed between said apertures in said moveable member, and a one way valve allowing flow only in the direction from said first opening to said second opening.
- 30 6. A device as claimed in any one of claims 2 to 5 wherein said first auxiliary outlet is of an cross sectional area greater than that of said second auxiliary outlet.
7. A device as claimed in claim 4 wherein said body portion including stopping means restricting the axial movement of said movable member such that during inhalation said

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moveable member moves towards said second opening until stopped by said stopping means whereby said apertures in said body portion are closed off by said solid sections, and during exhalation said moveable member moves toward said first opening until stopped by said stopping means whereby said apertures in said moveable member align with said apertures in said body portion.

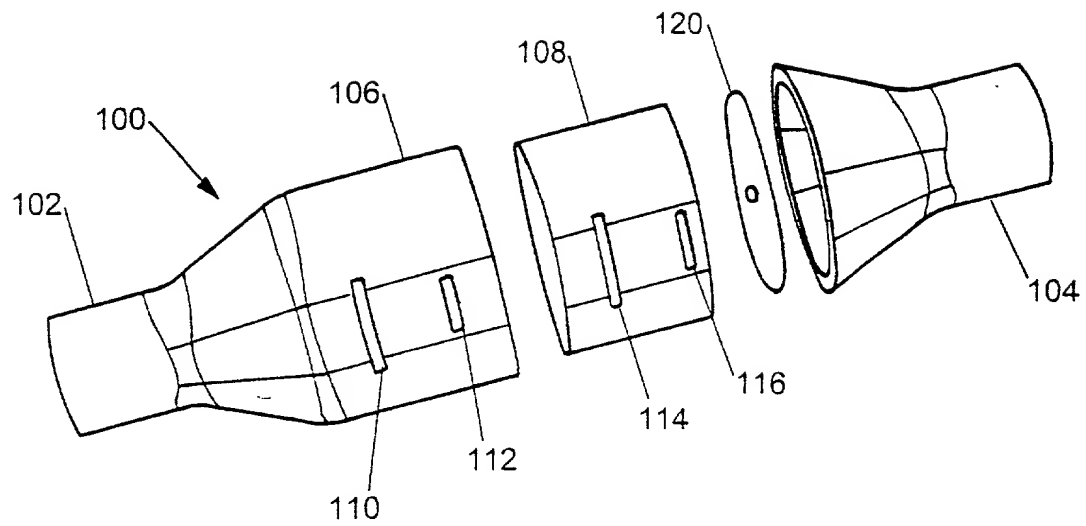
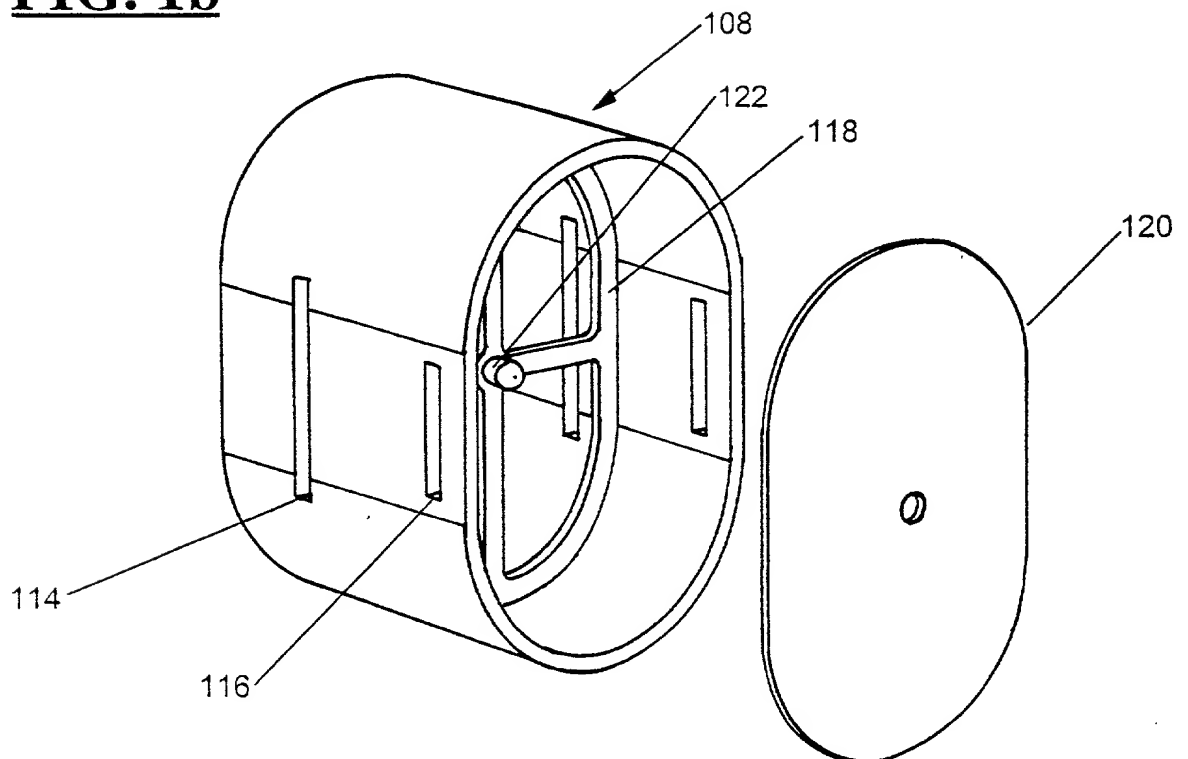
8. A system for supplying gases to a user at a pressure above ambient comprising:  
a pressurised gases supply,  
gases delivery means for supplying said gases to said user in fluid communication with  
said pressurised gases supply and said user, and  
flow control means disposed within said gases delivery means or in fluid communication therewith, said flow control means comprising a device according to any one of the preceding claims.

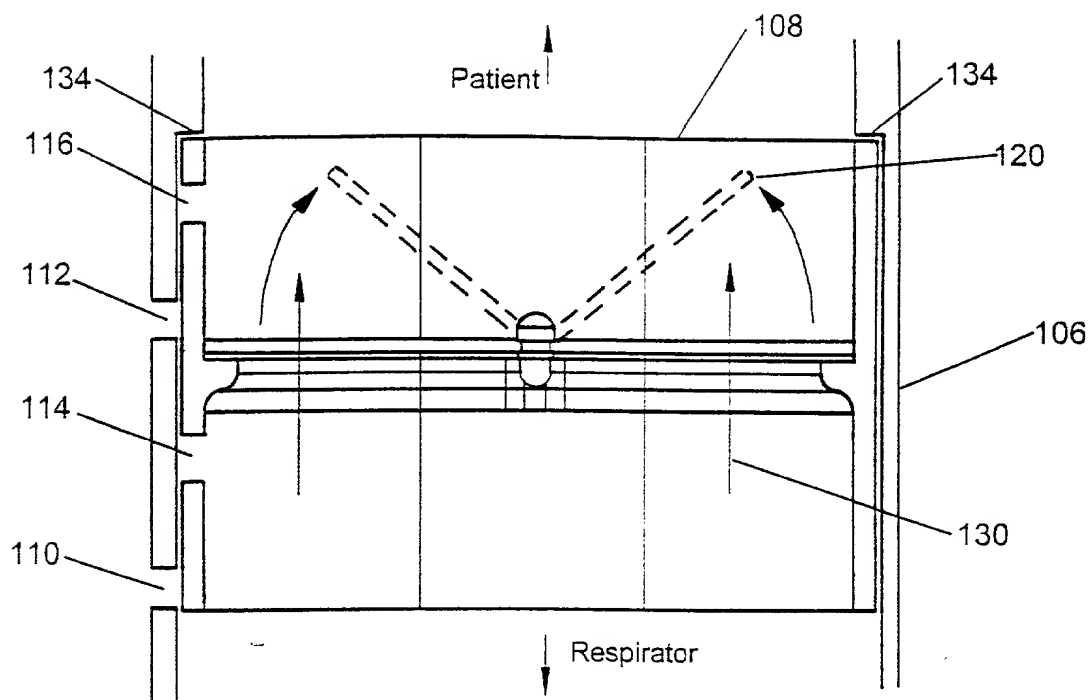
9. A system as claimed in claim 8 further comprising humidification means, for humidifying said gases before delivery to said user, disposed within or in fluid communication with said gases delivery means.



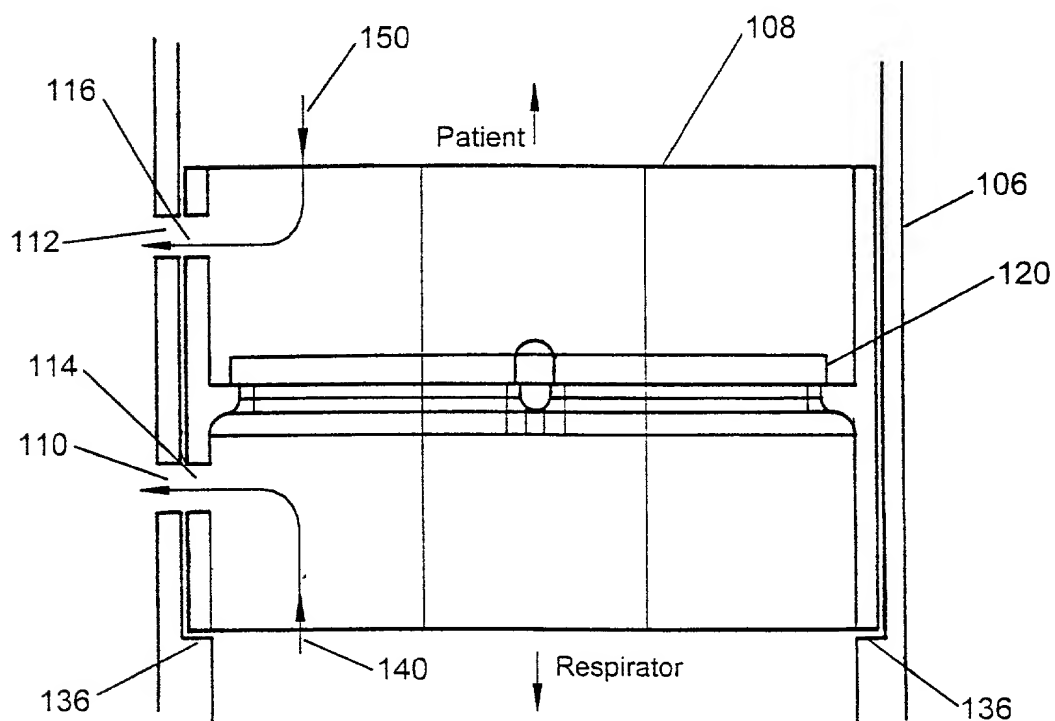
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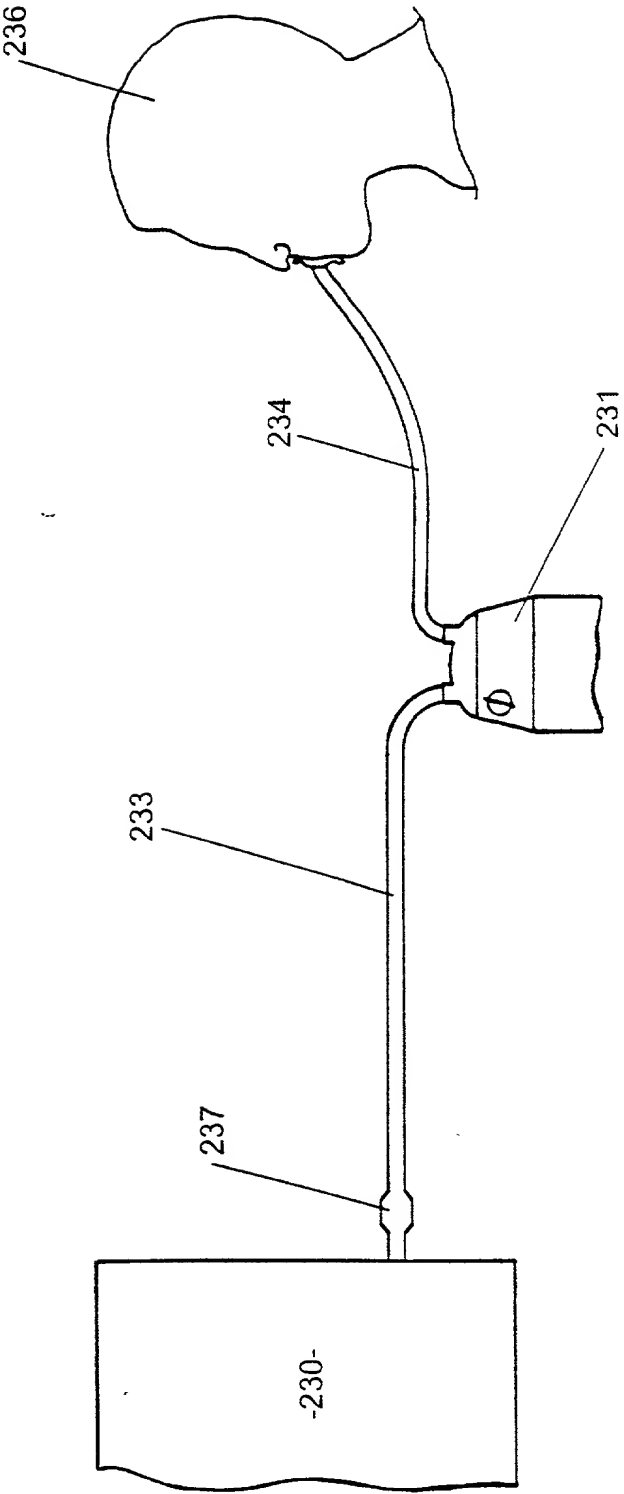
**FIG. 1a****FIG. 1b**



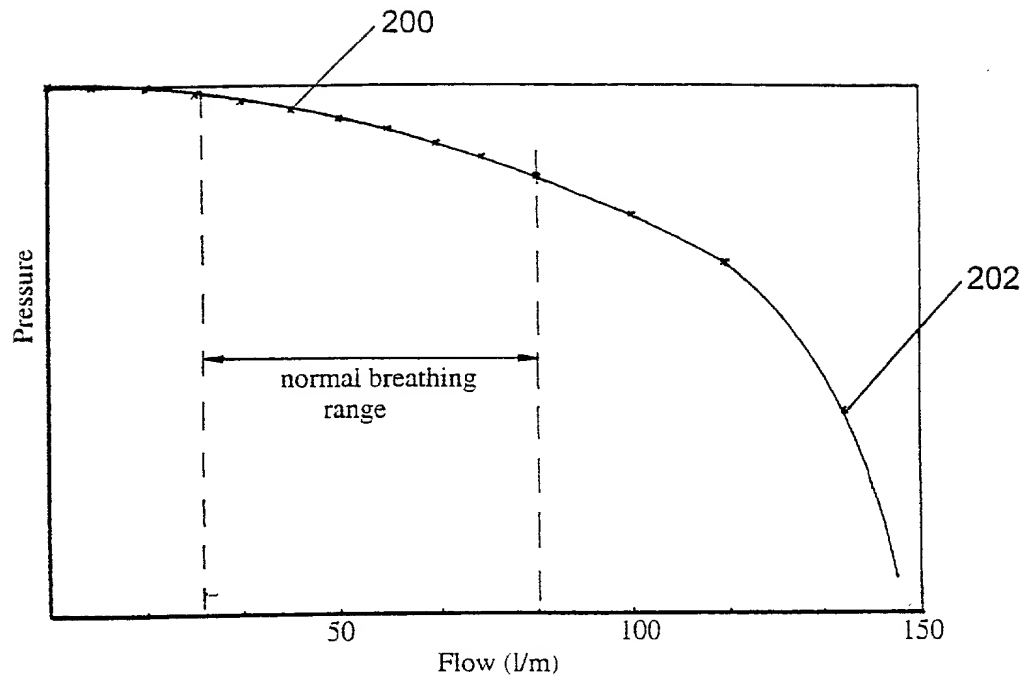
**FIG. 2**



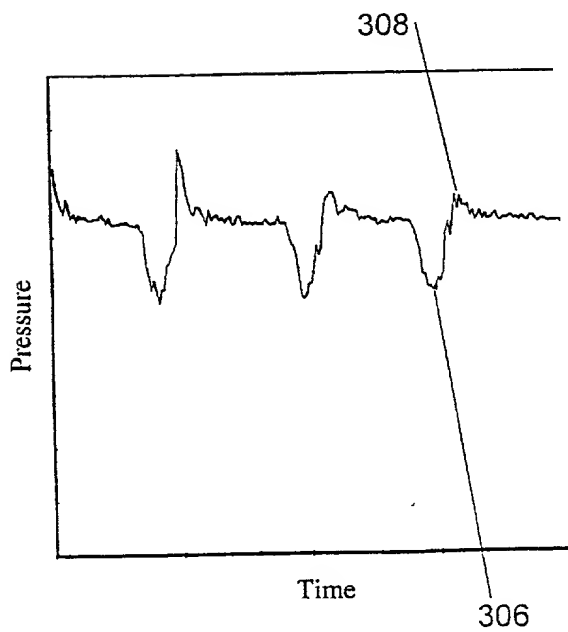
**FIG. 3**



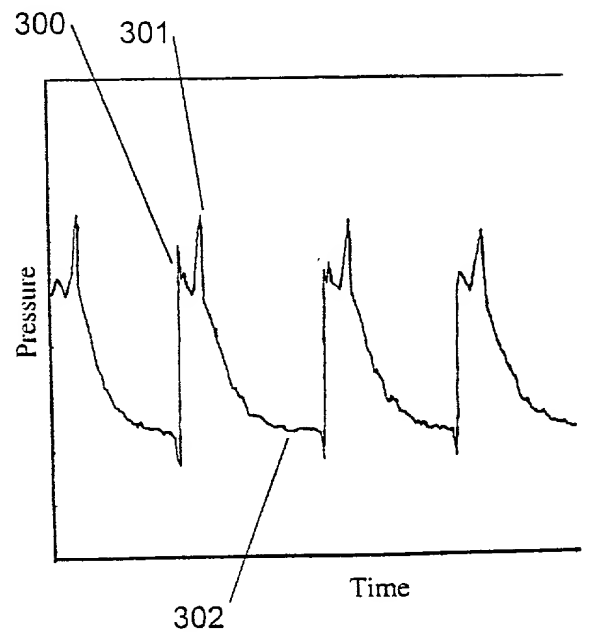
**FIG. 5**



**FIG. 4**



**FIG. 6**



**FIG. 7**

## DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**BREATHING ASSISTANCE APPARATUS**, the specification of which

(check one) ☒ is attached hereto.  
☐ was filed on \_\_\_\_\_ as  
 Application Serial No. \_\_\_\_\_  
 and was amended on \_\_\_\_\_  
 (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

## Prior Foreign Application(s)

## Priority Claimed

<u>337993</u> (Number)	<u>New Zealand</u> (Country)	<u>23 September 1999</u> (Day/Month/Year Filed)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below; insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status: patented, pending, abandoned)
_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status: patented, pending, abandoned)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Richard A. Giangiorgi, Reg. 24,284; Raiford A. Blackstone, Jr., Reg. 25,156; David J. Marr, Reg. 32,915; Linda L. Palomar, Reg. 37,903; James R. Foley, Reg. 39,979; James A. O'Malley, Reg. 45,952 and Paige A. Kitzinger, Reg. 45,219.

SEND CORRESPONDENCE TO: **TREXLER, BUSHNELL, GIANGIORGI & BLACKSTONE, LTD.**  
 105 W. ADAMS STREET, CHICAGO, IL 60603

DIRECT TELEPHONE CALLS TO: (312) 704-1890 RAIFORD A. BLACKSTONE, JR.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor NICHOLAS CHARLES ALAN SMITH

Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

Residence Auckland, New Zealand  
 Citizenship New Zealand  
 Post Office Address 157 Great South Road, Auckland, New Zealand

(Supply similar information and signature for second and subsequent joint inventors.)

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POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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SEND CORRESPONDENCE TO: TREXLER, BUSHNELL, GIANGIORGI & BLACKSTONE, LTD.  
105 W. ADAMS STREET, CHICAGO, IL 60603

DIRECT TELEPHONE CALLS TO: (312) 704-1890 RAIFORD A. BLACKSTONE, JR.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of second inventor ALASTAIR EDWIN McAULEY

Inventor's signature Date

Residence Auckland, New Zealand

Citizenship New Zealand

Post Office Address 5/27 Lucerne Road, Remuera, Auckland, New Zealand

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